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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,008	11/18/2003	Ling Yuk Cheung	KONG-28	6735
1473 7590 12/27/2006 FISH & NEAVE IP GROUP ROPES & GRAY LLP 1251 AVENUE OF THE AMERICAS FL C3 NEW YORK, NY 10020-1105			EXAMINER SRIVASTAVA, KAILASH C	
			ART UNIT	PAPER NUMBER
			1657	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/27/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/717,008

Applicant(s)

CHEUNG, LING YUK

Examiner

Dr. Kailash C. Srivastava

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/20/2004 & 3/7, 3/24 & 4/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment and response filed 16 October 2006 to Election requirement in Office Action mailed 14 June 2005 is acknowledged and entered.
2. The Art Unit Location for your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) has been changed to Art Unit 1657. To aid in correlating any papers for this application (i.e., 10/717,008), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

Claims Status

3. Claims 1- 10 are pending.
4. Claim 10 has been amended.
5. Claims 1-9 have been withdrawn.
6. Claim 10 is examined on merits.

Restriction/Election

7. Applicant's election without traverse of Group IV, Claim 10 in the response filed 16 October 2006 is acknowledged and entered.
8. Claim 10 is examined on merits

Information Disclosure Statement

9. Applicant's Information Disclosure Statements (i.e., IDS) filed 20 April 2004 and 7 March, 24 March and 11 April 2005 are acknowledged, made of record and have been considered.

Objection To Title

10. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed, which is a method to prepare compositions comprising yeast treated with electromagnetic energy. Examiner suggests the

following title for the instant invention. "A Method To Prepare a Composition Comprising Culturing Yeasts in Presence of Alternating Electric Current".

Double Patenting

11. The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 12-13 of each of U.S. Patent Numbers 6,984,507; 6,984,508; 6,987,012 and 6,989,253. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method comprising culturing a plurality of yeast cells of *Saccharomyces cerevisiae* in presence of electric field of certain frequency expressed in MHz and at certain field strength expressed in mV/cm to prepare a yeast composition is a substantially similar process to one that is Claimed in Claim 10 of the instant application.

13. Claim 10 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 13 of co-pending Application Number 10/185,276 and Claims 13-17 of co-pending Application Number 10/184,749. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method comprising culturing a plurality of yeast cells of *Saccharomyces cerevisiae* in presence of electric field of certain frequency expressed in MHz and at certain field strength expressed in mV/cm to prepare a yeast composition is a substantially similar process to one that is Claimed in

Claim 10 of the instant application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claim 10 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 17-21 of co-pending Application Number 10/460,323; Claims 17-21 of co-pending Application Number 10/460,336; Claims 17-21 of co-pending Application Number 10/460,341; Claims 17-21 of co-pending Application Number 10/460,833; Claims 17-21 of co-pending Application Number 11/226,670; Claims 17-21 of co-pending Application Number 11/226,671; Claims 17-21 of co-pending Application Number 11/226,672 and Claims 17-21 of co-pending Application Number 11/226,673.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the method comprising culturing a plurality of yeast cells of *Saccharomyces cerevisiae* in presence of electric field of certain frequency expressed in MHz and at certain field strength expressed in mV/cm to prepare a yeast composition is a substantially similar process to one that is Claimed in Claim 10 of the instant application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claim 10 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 30-36 and 43 of each of the following co-pending non-provisional United States Patent Application Numbers 10/460,246; 10/460,247; 10/460,271; 10/460,324; 10/460,325; 10/460,326; 10/460,328; 10/460,337; 10/460,338; 10/460,437; 10/460,438; and 10/460,530; 10460,832 and 10/460,833. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method comprising culturing a plurality of yeast cells of *Saccharomyces cerevisiae* in presence of electric field of certain frequency expressed in MHz and at certain field strength expressed in mV/cm to prepare a yeast composition is a substantially similar process to one that is Claimed in Claim 10 of the instant application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claim 10 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 9 of Co-pending U.S. Non-Provisional Application Number 10/717, 134 and Claim 10 of Co-pending U.S. Non-Provisional Application

Number 10/717, 275. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method comprising culturing a plurality of yeast cells of *Saccharomyces cerevisiae* in presence of electric field of certain frequency expressed in MHz and at certain field strength expressed in mV/cm to prepare a yeast composition is a substantially similar process to one that is Claimed in Claim 10 of the instant application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 U.S.C. § 112

35 U.S.C. § 112, First Paragraph

17. The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claim 10 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the a specific strain of a microorganism, i.e., *Saccharomyces cerevisiae* AS2.562 is recited in the claims, said *Saccharomyces cerevisiae* AS2.562 is essential to the invention recited in those claims. Therefore, the *Saccharomyces cerevisiae* AS2.562 obtained after treating a yeast with a plurality of electromagnetic fields should be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, a deposit of the microorganism may satisfy the requirements of 35 U.S.C. §112.

It is noted that applicants have deposited the *Saccharomyces cerevisiae* AS2.562 but there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- a. during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- b. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- c. the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- d. the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807, which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- i. The name and address of the depository;
- ii. The name and address of the depositor;
- iii. The date of deposit;
- iv. The identity of the deposit and the accession number given by the depository;
- v. The date of the viability test;
- vi. The procedures used to obtain a sample if the test is not done by the depository; and
- vii. A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- i. The accession number for the deposit;
- ii. The date of the deposit.

35 U.S.C. § 112, Second Paragraph

19. Following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

20. Claim 10 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- From the currently presented claim language in Claim 10, it is not clear whether *Saccharomyces cerevisiae* Hansen AS2.562 is the yeast strain obtained after culturing commercially available plurality of *Saccharomyces cerevisiae* yeast cells to the claimed alternating electric field of a plurality of particular frequency and field strength for a given amount of time, or it is the *Saccharomyces cerevisiae* Hansen AS2.562 that is cultivated in alternating electric field of a plurality of particular frequency and field strength for a given amount of time. Appropriate clarification is required.

Claim Rejections - 35 U.S.C. § 103

21. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. Claim 10 is rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Zhang (U.S. Patent 5,578,486) in view of Zhang et al (Bioelectrochemistry and Bioenergetics, 28:341-358, 1992).

Claim recites a method to prepare a biological composition by culturing *Saccharomyces cerevisiae* yeast cells in presence of an alternating electric field of a plurality of particular frequency and field strength for a given amount of time.

Zhang (U.S. Patent 5,578,486, i.e., Zhang'486) teaches a method to prepare a biological composition comprising bacteria and yeast via treating said microorganisms with electromagnetic force of certain frequency and amplitude for a given period of time. Zhang further teaches the general concept of treating microorganisms with electromagnetic fields to selectively isolate microorganisms with enhanced physiological properties to assimilate certain nutrients and to de-select the microorganisms that do not have the requisite properties (Column 7, Lines 6-10; Lines 33-45 and Lines 57-60). The biological composition prepared according to Zhang's method comprises growth factor producing yeast, *Saccharomyces diastaticus*, ATCC 55597 and the energy producing yeast, *Saccharomyces sinenses* (Column 3, Lines 56-57; Column 4, Lines 36-39). Zhang also teaches a method to apply a plurality of electromagnetic field (i.e., EMF) of varying amplitudes and frequencies for making said biological compositions (Column 6, Lines 14-15; Column 7, Lines 6-10; Lines 33-45 and Lines 57-60), Zhang'486 does not explicitly demonstrate that yeast were exposed to EMF for a certain duration. Zhang et al (Bioelectrochemistry and Bioenergetics, 1992) teach culturing *Saccharomyces* yeasts under careful control of temperature, pH and glucose concentration to expose *Saccharomyces cerevisiae* cells for a duration of at least 30 mins to EMF (Figure 1; Page 345, Lines 11-18; Lines 23-31; Lines 35-43 and Page 347, Lines 1-2 below Figure 4) with EMF.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Zhang with those from Zhang et al. to obtain a method to culture yeasts with a plurality of electromagnetic fields of varying amplitude and frequency to create yeast strains cultured in presence of electromagnetic force, wherein said yeasts are *Saccharomyces* yeast, because individual and combined teachings from each one of Zhang and Zhang et al. teach a method to culture yeasts in presence of a plurality of

electromagnetic fields of varying amplitude and frequency for a certain duration, wherein said yeasts are *Saccharomyces cerevisiae*.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Zhang'486 according to the teachings from Zhang et al. to obtain a method to cultivate yeasts with a plurality of electromagnetic fields of varying amplitude and frequency, wherein said yeasts are *Saccharomyces yeast*, because Zhang and Zhang et al. teach the methods to cultivate *Saccharomyces yeast* applying same components and steps as instantly claimed and Zhang further teaches to make a biological composition applying said method to treat yeast with a plurality of electromagnetic fields of different amplitudes and frequencies. The prior art despite not disclosing the same exposure times of EMF as instantly claimed give a range of time for which the microorganisms should be EMF-treated. The prior art references do not teach the same exact *Saccharomyces cerevisiae* strain or amplitudes and frequencies of electromagnetic fields or duration for which the yeast strains are exposed to a given EMF as instantly claimed. However, the adjustment of particular conventional working conditions (e.g., concentration of a particular component in a given method, range of temperature, pressure, exposure time, and other experimental parameters that are interchanged for the same effect) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter, which is well within the purview of the skilled artisan.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

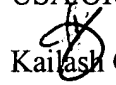
Conclusion

23. For reasons aforementioned, no Claims are allowed.


24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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December 18, 2006


CHRISTOPHER R. TATE
PRIMARY EXAMINER